



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, DC 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/817,704    08/25/97    SWAAK

A    P8214-7002

EXAMINER
----------

CUNNINGHAM, T

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED:

03/31/98

HM11/0331  
NIKAIDO MARMELESTEIN MURRAY & ORAM  
METROPOLITAN SQUARE  
655 15TH STREET NW  
SUITE 330 G STREET LOBBY  
WASHINGTON DC 20005-5701

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/817,704**

Applicant(s)  
**Swaak, A. J.**

Examiner  
**Thomas Cunningham**

Group Art Unit  
**1644**



☒ Responsive to communication(s) filed on 5/5/97

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-13 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part of Paper No. 6

Serial Number: 08/817,704

Art Unit: 1644

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. "Use claims" are not statutory subject matter under U.S. patent law.

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

4. Claims 1 and 7 are rejected under 35 U.S.C. 112, second paragraph as failing to particularly point out and distinctly claim the invention. In claims like claim 1 and 7 it is unclear what the scope of the term "erythropoietin-like activity" is. Does this term limit the claim to a particular functional activity, or is it nonlimiting in that any activity, e.g. presence of a crossreactive epitope, is encompassed?

5. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph as lacking adequate enablement. One with skill in the art would not be able to identify without undue experimentation erythropoietin-like compounds without some indication of the desired functional activity and

Serial Number: 08/817,704

Art Unit: 1644

some indication of conserved structure. It would be necessary to determine all the known and unknown functional activities of erythropoietin and then to determine which compounds had similar activities.

B. Claims 1-13 are not enabled because they do not set forth definite steps that would allow one with skill in the art to either prepare or use therapeutically erythropoietin or erythropoietin-like compounds. For instance, claim 1 does not set forth definite physical steps that lead from erythropoietin to a pharmaceutical preparation, e.g. purifying erythropoietin, compounding it with a pharmaceutically-acceptable excipient, administering a particular dosage, etc.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas M. Cunningham, Ph.D, J.D. whose telephone number is (703) 308-3968. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

TC  
THOMAS M. CUNNINGHAM  
PRIMARY EXAMINER  
GROUP 1800